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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,304	06/29/2001	Rod Ross	155615-0024	2393

1622 7590 05/07/2003

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,304

Applicant(s)

ROSS ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 32-44, 46 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 13 is objected to because of the following informalities: "said blade having a recess" in line 5 should be "said blade *holder* having a recess". Appropriate correction is required.
2. Claim 21 is objected to because of the following informalities: "said blade" in line 5 should be "said blade holder". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 13,16,17,20 are rejected under 35 U.S.C. 102(e) as being anticipated by US

Patent No. 6,165,189 to Ziemer.

Ziemer discloses a microkeratome device that includes a blade holder (3) and blade (4). As shown in Figure 8C, the blade (4) includes a cutting edge (5), a rear edge, and side edges. The blade holder (3) has a recess (59) that receives the pin of the microkeratome device (column 3, lines 61-62). The blade holder further includes two cavities, which are more clearly labeled on Attachment A.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,2,6-8,12,29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,051,009 to Hellenkamp et al. in view of US Patent No. 4,759,363 to Jensen.

Hellenkamp discloses a microkeratome device that includes a blade (310) with a cutting edge (313) and blade holder (320) that defines a cutting depth. The blade holder further includes a recess (326) and the holder extends from the rear edge of the blade, as shown in Figure 6B. The cutting depth is defined between the cutting edge of the blade and the front surface of the blade holder.

The Hellenkamp microkeratome includes a pin (135), as shown in Figure 9. On page 11 of the specification of the application, applicant explains that the recess in the blade holder receives the pin (lines 9-10).

Hellenkamp includes all the limitations of claims 1,2,6-8,12,29-31, except for the blade holder having having a color that corresponds to the cutting depth of the blade. Jensen discloses a cutting blade with a blade holder. Jensen teaches that blade holders should be color coded to define different cutting depths (column 6, lines 18-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to color code the blade holder of Hellenkamp, as taught by Jensen, so that different cutting depths may be clearly defined.

5. Claims 3,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in view of Jensen, as applied to claim 2 above, and further in view of Richey.

Hellenkamp, as modified by Jensen above, includes all the limitations of claim 3, except for a raised surface on the front surface of the blade holder. Richey teaches that the front surface of a blade holder (42) can include a raised surface (44C), as shown in Figure 5. Figure 7 illustrates a plurality of raised surfaces (44E). Richey teaches that this structure helps to secure the blade holder to the microkeratome by friction fit (column 4, lines 25-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a raised surface on the front of the blade holder of the modified Hellenkamp device, as taught by Richey, as this provides a more secure fit between the blade holder and microkeratome.

6. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziemer in view of Jensen.

Ziemer includes all the limitations of claims 4 and 10, except for the blade holder having a color. Zierner does state that the blade and blade holder assembly are replaceable and disposable (column 6, line 60). . Jensen discloses a cutting blade with a blade holder. Jensen teaches that blade holders should be color coded to define different cutting depths (column 6, lines 18-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to color code the blade holder of Zierner, as taught by Jensen, so that different cutting depths may be clearly defined.

7. Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in view of Jensen, as applied to claim 1 above, and further in view of US Patent No. 6,228,099 to Dybbs.

Hellenkamp, as modified by Jensen, includes all the limitations of claims 5 and 11, except for a bonding agent and a hole. The blade and blade holder are interlocked by holes on the blade and protrusions on the blade holder (Figures 6A-6C). It would have been obvious to one of ordinary skill in the art at the time the invention was made to reverse the interlocking structure so that the holes are on the blade holder, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. Dybbs discloses a microkeratome with a blade (98) and blade holder (100,96). Dybbs teaches that adhesive can be used with interlocking structures of a blade assembly (column 9, lines 35-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply adhesive to the interlocking structure of the blade and blade holder of the Hellenkamp device, as taught by Dybbs, as the addition of adhesive ensures a more secure attachment between two interlocking parts of a blade assembly.

8. Claims 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziemer in view of Dybbs.

Ziemer includes all the limitations of claims 15 and 19, except for a bonding agent and a hole. The blade and blade holder are interlocked by holes on the blade and protrusions on the blade holder (Figure 8B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to reverse the interlocking structure so that the holes are on the

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blade holder, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. Dybbs discloses a microkeratome with a blade (98) and blade holder (100,96). Dybbs teaches that adhesive can be used with interlocking structures of a blade assembly (column 9, lines 35-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply adhesive to the interlocking structure of the blade and blade holder of Ziemer, as taught by Dybbs, as the addition of adhesive ensures a more secure attachment between two interlocking parts of a blade assembly.

9. Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziemer in view of Richey.

Ziemer includes all the limitations of claims 14 and 18, except for the front surface of the blade holder including a raised surface. Richey teaches that the front surface of a blade holder (42) can include a raised surface (44C), as shown in Figure 5. Figure 7 illustrates a plurality of raised surfaces (44E). Richey teaches that this structure helps to secure the blade holder to the microkeratome by friction fit (column 4, lines 25-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a raised surface on the front of the blade holder of Ziemer, as taught by Richey, as this provides a more secure fit between the blade holder and microkeratome.

10. Claims 21,23,24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in view of US Patent No. 6,228,099 to Dybbs.

Hellenkamp includes all the limitations of claims 21 and 24, except for a bonding agent and a hole. The blade and blade holder are interlocked by holes on the blade and protrusions on the blade holder (Figures 6A-6C). It would have been obvious to one of ordinary skill in the art at the time the invention was made to reverse the interlocking structure so that the holes are on the blade holder, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. Dybbs discloses a microkeratome with a blade (98) and blade holder (100,96). Dybbs teaches that adhesive can be used with interlocking structures of a blade assembly (column 9, lines 35-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply adhesive to the interlocking structure of the blade and blade holder of the Hellenkamp device, as taught by Dybbs, as the addition of adhesive ensures a more secure attachment between two interlocking parts of a blade assembly.

11. Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in view of Dybbs, as applied to claims 21 and 24 above, and further in view of Richey.

Hellenkamp, as modified by Dybbs above, includes all the limitations of claims 22 and 25, except for the front surface of the blade holder including a raised surface. Richey teaches that the front surface of a blade holder (42) can include a raised surface (44C), as shown in Figure 5. Figure 7 illustrates a plurality of raised surfaces (44E). Richey teaches that this structure helps to secure the blade holder to the microkeratome by friction fit (column 4, lines 25-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a raised surface on the front of the blade holder of the modified Hellenkamp device, as

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taught by Richey, as this provides a more secure fit between the blade holder and microkeratome.

12. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in view of US Patent No. 6,451,039 to Richey, Jr. et al.

As explained above, Hellenkamp includes all the limitations of claims 27 and 28, except for a raised surface on the front surface of the blade holder. Richey teaches that the front surface of a blade holder (42) can include a raised surface (44C), as shown in Figure 5. Figure 7 illustrates a plurality of raised surfaces (44E). Richey teaches that this structure helps to secure the blade holder to the microkeratome by friction fit (column 4, lines 25-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a raised surface on the front of the blade holder of Hellenkamp, as taught by Richey, as this provides a more secure fit between the blade holder and microkeratome.

13. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hellenkamp in view of US Patent No. 5,651,782 to Simon et al.

Hellenkamp, as explained above, includes all the limitations of claim 45, except for an opening that extends through the blade and is located between the cutting edge and front surface. Simon discloses a device that includes a cutting blade (12) with a cutting edge (22) and blade holder (16), as shown in Figure 2. Simon teaches that a blade used in eye surgery should include an opening (18) located between the cutting edge and front surface of the blade holder, because the opening acts as a window, allowing the surgeon to view a greater portion of the eye during

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surgery (column 4, lines 57-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an opening in the blade of Hellenkamp, as taught by Simon, as this allows the surgeon to view a greater portion of the eye during surgery.

Response to Arguments

14. Applicant's arguments with respect to claims 1-31 and 45 have been considered but are moot in view of the new ground(s) of rejection. Examiner has rejected the claims under 103, due to the amendments to the claims. To clarify, the opening (18) of Simon '782 does extend all the way through the blade, as clearly indicated by the dashed lines in Figure 1.

Note: the 4th paragraph on page 5 is confusing, because the name "Simon" was changed to "Cohn" in the middle of the argument.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

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April 30, 2003


Michael Milano
Supervisory Patent Examiner
Art Unit 3731